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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,426	02/18/2004	David J. Jorgenson	P0008050.05	3045

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EXAMINER	
HOLMES, REX R	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
02/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,426	JORGENSON ET AL.	
	Examiner	Art Unit	
	REX HOLMES	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. This action is made final as it based on the amendments to the claims that were filed on 03/27/08. The amendments that were made were in response to the rejection of 12/27/07.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 17-21 are rejected under 35 U.S.C. 101 as the claimed invention is directed to non-statutory subject matter. Process claims that do not transform underlying subject matter (such as an apparatus, composition, or article of manufacture) to a different state or thing and are not tied to another statutory class (an apparatus, composition, or article of manufacture) are not statutory subject matter. See Diamond v. Diehr, 450 U.S. 175, 184 (1981) (quoting Benson, 409 U.S. at 70), Parker v. Flook, 437 U.S. 584, 588 n.9 (1978) (citing Cochrane v. Deener, 94 U.S. 780, 787-88 (1876)), and In re Comiskey, 499 F.3d 1365, 1376 (Fed. Cir. 2007) (request for rehearing en banc pending). In this case claim 17 has no connection to a machine and produces no useful tangible result since a determination has not been accomplished.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 17-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 17 states that it uses sensed signals, and collecting data relating to one of an assortment of things. Then processing the collected data to determine if a lead status event occurred. The specification states that, "The LSM employs a set of weighted sum rules used by algorithms to process data from the above-mentioned sources to arrive at easily interpreted messages accessible to clinicians via the external programmer". Thus the specification does not support using just one collected data but using all of them. Further the specification states that it collects impedance data and threshold data.

5. Claims 17-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 17 recites sensing in two distinct pathways and then collecting data relating to one of a assortment of things. The Specification does state that two sensing pathways are used to measure impedance as listed on page 15, line 33 to Page 16 line 3. It is further noted that this is a different embodiment than the embodiment that

utilizes the collected data relating to things other than impedance. The specification does not have support for using two distinct pathways to collecting data relating to one of a percent of time in mode switch, R-wave amplitude, P-wave amplitude, reversion pace count, refractory sense count, high rate episode count, and time from implant.

6. Claims 17-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 17 recites sensing in two distinct pathways and then collecting data relating to one of an assortment of things and then applying the algorithm to each distinct pathway. The specification does not have support for using two distinct pathways to collecting data relating to one of a percent of time in mode switch, R-wave amplitude, P-wave amplitude, reversion pace count, refractory sense count, high rate episode count, and time from implant and then determining a lead event. The specification provides support for checking for Non-Physiological sensed events on a unipolar and bipolar channel, but does not provide support for running two different determination criteria on the separate pathways.

7. Claims 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 22, line 12, states, "identifying the presence of a lead-related condition

...." The specification states in multiple places that the sensed events "may be an indicator" and that they are "potential indicators", not that they identify the presence of a lead-related condition. It is suggested that the applicant change line 12 to say, "potential presence", and to change the preamble to say,"A method of distinguishing the potential presence of lead-related conditions in a medical device ...."

8. Claims 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is silent as generating a first and second event count based on two different pathways. Although, the specification does state that it tests for events in both bipolar and unipolar mode it does not state if creates a second event count. Further the specification is silent as to identifying the presence of a lead related condition in response to a first event count and a second event count.

9. It is noted that the applicant discloses multiple alternate embodiments and that the embodiments are not disclosed as being used together.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. The preamble of claim 17 is inconsistent with the claim body as no determination or monitoring of lead status has been actively recited and claimed. In line 10, "to determine ..." is not a positive recitation of the determination. It is suggested to state, “and determining a lead status event has occurred from said processed data”.

13. Claim 17 is lacking a connection/nexus between the sensing signals along two distinct pathways vs the collected data. Is the sensing signals also used in the lead status determination—the claim does not set this forth.. In line 12, “and wherein a first determination criterion…” is vague since the determination criterion has been set forth (line 11-12) to be used with the “collected data” and not the “sensed signals”. It is further unclear if the sensed signals are also being referred to as the collected data? Further, if the sensed signals are collected data, does this mean that the claim needs both the sensed signals and collected data or just “one of…” like line 6.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Schuelke et al. (U.S. Pat. 5,755,742 hereinafter “Schuelke").

16. Regarding claim 17, Schuelke discloses a system that includes a implantable device that allows for sensing in multiple pathways (e.g. Col. 15, ll. 30-40), that also senses a p-wave amplitude (e.g. Col. 10, ll. 15-28), and further processes the data for

each pathway to determine if there is a lead related event (e.g. Col. 16, ll. 43-58; see also Abstract).

17. Regarding claim 18, Schuelke discloses that the system further alerts a user if a lead condition occurs (e.g. Col. 15, ll. 9-25).

18. Regarding claim 19, Schuelke discloses that the system detects if it is a lead conductor or insulation issue (e.g. Col. 15, ll. 30-40).

19. Claims 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Gillberg et al. (U.S. Pat. 5,713,932 hereinafter "Gillberg").

20. Regarding claims 22-23, Gillberg discloses a method of determining lead dislocation that utilizes bipolar and unipolar electrodes to sense conduction times in each chamber of the atrium, then determining intervals and incrementing a test counter for each chamber. Then if the counter reaches a value it identifies a lead dislocation (e.g. Figs. 5-7; Cols. 14-16).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schuelke as applied to claims 17-19 above, and further in view of Paul et al. (U.S. Pat. 5,814,088 hereinafter "Paul").

24. Schuelke discloses the claimed invention except for the lead status event being a biological interface issue. However, Paul teaches that it is known to use a biological interface issue as a lead status event as set forth in Col. 11, ll. 20-23 to provide a further reason why a lead failed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Schuelke, with the biological interface issues as taught by Paul, since such a modification would provide the predictable results of a lead failure monitoring system for providing a more informative system to show loss of lead function due to both lead failure and lead dislocation.

Allowable Subject Matter

The indicated allowability of claim 24 is withdrawn in view of the 112 rejection of claims 22-24.

Response to Arguments

25. The Applicant argues that Schuelke does not process the data determine if a lead status event has occurred. The Examiner notes that the applicant does not

actively recite that the processing of the data makes a determination only that the lead status was determined. Schuelke processes the p-wave amplitude and further determines the lead status.

Conclusion

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762